

Notice of Allowability

Application No.

09/491,500

Examiner

Anne-Marie Falk, Ph.D.

Applicant(s)

BLACK ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 3/15/05.
2. ☒ The allowed claim(s) is/are 1,4-6,11-18,110-114,119-130 and 139-166.
3. ☒ The drawings filed on 04 November 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Anne-Marie Falk
Anne-Marie Falk, Ph.D.
Primary Examiner
Art Unit: 1632

Art Unit: 1632

Examiner's Amendment

The response filed December 13, 2004 has been entered. The amendment filed December 13, 2004 has not been entered due to an error in the claims listing.

The amendment filed March 15, 2005 has been entered. Claims 11, 12, 129, 130, 141, and 157 have been amended.

The declaration of Dr. Keith L. Black, filed December 13, 2004, has been entered.

Claims 1-6, 11-18, 97-100, and 106-199 are pending in the instant application.

Claims 97-100, 106-109, 124-138, 140-152, 156-166, and 167-199 were withdrawn from consideration pursuant to 37 CFR 1.142(b), as being directed to a nonelected invention or nonelected species, there being no allowable generic claim.

Claims 124-130, 140-152, and 156-166 are rejoined to the examined claims.

Claims 97-100, 106-109, 131-138, and 167-199 remain withdrawn from consideration pursuant to 37 CFR 1.142(b), as being directed to a nonelected invention or nonelected species, there being no allowable generic claim.

Accordingly, Claims 1-6, 11-18, 110-130, and 139-166 are under consideration.

During a telephone conversation conducted on March 14, 2005, Rebecca Kaufman authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the Claims:

Claims 2, 3, 97-100, 106-109, 115-118, 131-138, and 167-199 are cancelled.

1. A method of delivering a medicant to [an abnormal brain region] a brain tumor in a mammalian subject, comprising:

Art Unit: 1632

administering to a mammalian subject having [an abnormal brain region] a brain tumor an agonist of an ATP-sensitive potassium channel, under conditions an in an amount sufficient to increase the permeability to the medicant of a capillary or arteriole delivering blood to cells of the [abnormal brain region] brain tumor; and

administering to the subject simultaneously or substantially simultaneously with the agonist the medicant so that the medicant is delivered selectively to the cells of the [abnormal brain region] brain tumor compared to normal brain regions.

18. A method of selectively delivering a medicant to [an abnormal brain region] a brain tumor in a mammalian subject, comprising:

administering to a mammalian subject having [an abnormal brain region] a brain tumor an agonist of an ATP-sensitive potassium channel, under conditions an in an amount sufficient to increase potassium flux through an ATP-sensitive potassium channel in an endothelial cell membrane of a capillary or arteriole delivering blood to cells of the [abnormal brain region] brain tumor, whereby the capillary or arteriole is made more permeable to the medicant; and

administering to the subject simultaneously or substantially simultaneously with the agonist the medicant, so that the medicant is delivered selectively to the cells of the [abnormal brain region] brain tumor compared to normal brain regions.

119. The method of Claim 1, wherein the [abnormal brain region] brain tumor is a [region of] benign tumor [tissue].

120. The method of Claim 1, wherein the [abnormal brain region] brain tumor is a [region of] malignant tumor [tissue].

121. The method of Claim 1, wherein the [abnormal brain region includes] brain tumor is a glioma, glioblastoma, oligodendroglioma, astrocytoma, ependymoma, primitive neuroectodermal tumor, atypical meningioma, malignant meningioma, or neuroblastoma[, sarcoma, melanoma, lymphoma, or carcinoma].

122. The method of [any of] Claim 1, wherein the medicant is administered via intravenous, [intramuscular,] intra-arterial, or intracarotid injection or infusion.

Art Unit: 1632

153. A method of delivering a medicant to [an abnormal brain region] a brain tumor in a mammalian subject, comprising:

administering simultaneously or substantially simultaneously to a mammalian subject having [an abnormal brain region] a brain tumor (i) minoxidil or minoxidil sulfate and (ii) a medicant, under conditions and in an amount sufficient to increase the permeability to the medicant of a capillary or arteriole delivering blood to cells of the [abnormal brain region] brain tumor, so that the medicant is delivered selectively to the cells of the [abnormal brain region] brain tumor compared to normal brain regions.

154. A method of delivering a therapeutic cytotoxic agent to an abnormal brain region in a mammalian subject, comprising:

administering simultaneously or substantially simultaneously to a mammalian subject having [an abnormal brain region] a brain tumor (i) minoxidil or minoxidil sulfate and (ii) a therapeutic cytotoxic agent, under conditions and in an amount sufficient to increase the permeability to the [medicant] agent of a capillary or arteriole delivering blood to cells of the [abnormal brain region] brain tumor, so that the [medicant] agent is delivered selectively to the cells of the [abnormal brain region] brain tumor compared to normal brain regions.

155. The method of Claim 153, wherein the [medicant] agent is cisplatin or carboplatin.

156. The method of Claim 153, wherein the [medicant] agent is methotrexate.

157. The method of Claim 153, wherein the [medicant] agent is 5-fluorouracil.

158. The method of Claim 153, wherein the [medicant] agent is amphotericin.

159. The method of Claim 153, wherein the [medicant] agent is daunorubicin.

160. The method of Claim 153, wherein the [medicant] agent is doxorubicin.

161. The method of Claim 153, wherein the [medicant] agent is vincristine or vinblastine.

Art Unit: 1632

- 162. The method of Claim 153, wherein the [medicant] agent is busulfan.
- 163. The method of Claim 153, wherein the [medicant] agent is chlorambucil.
- 164. The method of Claim 153, wherein the [medicant] agent is cyclophosphamide.
- 165. The method of Claim 153, wherein the [medicant] agent is melphalan.
- 166. The method of Claim 153, wherein the [medicant] agent is ethyl ethanesulfonic acid.

The following is an examiner's statement of reasons for allowance:

The Declaration and post-filing art presented in the response filed December 13, 2004 demonstrate enablement for treating tumor tissue using the claimed method of the invention. The Declaration and post-filing art provide convincing evidence for delivering a variety of medicants, including antibodies, to a brain tumor, using the claimed method.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Upon entry of the foregoing amendment, Claims 1, 4-6, 11-18, 110-114, 119-130, and 139-166 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

Art Unit: 1632

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER